UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: February 23, 2010

SUBJECT: Efficacy Review for SDC3A;
EPA Reg. No. 72977-5;
DP Barcode: D371842

FROM: Lorilyn M. Montford
Efficacy Evaluation Team
Antimicrobials Division

THRU: Tajah Blackburn, Ph.D., Team Leader
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TO; Marshall Swindell, PM 33/Martha Terry
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APPLICANT: ETI H2O, Inc.
1725 Gillespie Way
El Cajon, CA 92020

FORMULATION FROM THE LABEL:

Active Ingredient(s)	% by wt
Silver	0.003%
Citric Acid	4.846%
Inert Ingredients	95.151%
Total	100.000%

I BACKGROUND

The product, SDC3A (EPA Reg. No. 72977-5), is an EPA-approved disinfectant (bactericide, fungicide, virucide) and deodorizer for use on hard, non-porous surfaces in household, commercial, institutional, food preparation, animal care, and hospital or medical environments. The applicant requested to amend the registration of this product to add new claims for effectiveness as a disinfectant against additional viruses and a new claim for effectiveness as a sanitizer on hard, non-porous, food contact surfaces. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to the Agency (dated November 13, 2009), six studies (MRID 479124-01 through 479124-06), Statements of No Data Confidentiality Claims for all six studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, Axen 30. The letter from the applicant's representative to EPA (dated November 13, 2009) states that the tested product, Axen 30, is identical in composition to the product, SDC3A, which is the subject of this efficacy report.

II USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The product may be used to treat hard, non-porous surfaces such as air conditioning vents, activity centers, appliances, baby furniture, bathtubs, bed frames, beverage bars, blenders, booster chairs, bottling equipment, breast pump parts, buffet counters, cabinets, cages, chairs, child car seats, chopping blocks, computer keyboards, coolers, counters, desks, diaper changing tables, diaper pails, dish racks, doorknobs, drain boards, drinking fountains, examination tables, faucet handles, floors, food processing equipment, grocery carts, handrails, jungle gyms, lab benches, laundry hampers, light switch covers, litter boxes, lunch boxes, patio furniture, picnic tables, playhouses, pre-mixing equipment, potty seats, remote controls, salad bars, showers, sinks, strollers, tables, tanning beds, telephones, toilets, toy boxes, toys, urinals, walls, waste containers, and wheelchairs. The proposed label indicates that the product may be used on hard, non-porous surfaces including: glass, glazed porcelain, glazed tile, metal, painted surfaces, and plastic. Directions on the proposed label provide the following information regarding use of the product:

> As a disinfectant against viruses: Pre-clean surfaces prior to using this product. Apply, spray, or mist surfaces until thoroughly wet. Surfaces must be completely wet for 10 minutes (or for the specific contact time specified on the product label for specific viruses). The surface may then be wiped dry with a clean towel.
>
> As a sanitizer on food contact surfaces: Pre-clean surfaces prior to using this product. Spray, pour, or spread this product on surface until thoroughly wet. Let stand for 60 seconds. Wipe with a clean towel or allow to air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces)

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution for the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 479124-01 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A (H1N1) virus" for Axen 30, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – October 26, 2009. Project Number A08285.

This study was conducted against Influenza A (H1N1) virus (Strain A/PR/8/34; ATCC VR-1469), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Division; maintained in-house) as the host system. Two lots (Lot Nos. P09209001 and P09210001) of the product, Axen 30, were tested according to ATS Labs Protocol No. IMS01090109.FLUA (copy provided). The product was received ready-to-use, along with trigger spray nozzles. The stock virus culture contained 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the undersides of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 40% relative humidity. For each lot of product, separate dried virus films were sprayed (4 sprays) with the product until thoroughly wet at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 1 or 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

2. MRID 479124-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Respiratory syncytial virus (RSV)" for Axen 30, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – August 15, 2007. Project Number A04703.

This study was conducted against Respiratory syncytial virus (Strain Long; ATCC VR-26), using Hep-2 cells (human larynx carcinoma cells; obtained from ViroMed Laboratories, Inc.; maintained in-house) as the host system. Two lots (Lot Nos. 2006.003.001 and 2007.008.002) of the product, Axen 30, were tested according to ATS Labs Protocol No. IMS01020807.RSV (copy provided). The product was received ready-to-use, and transferred to spray bottles for testing. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the undersides of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 18.5°C at 51% relative humidity. For each lot of product, separate dried virus films were sprayed (2 sprays) with the product until thoroughly wet at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 3 or 10 minutes at 18.5°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Eagles – Minimum Essential Medium supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL Fungizone, 10 mM Hepes, 10 µg/mL vancomycin, and 2.0 mM L-glutamine. Hep-2 cells in multi-well culture dishes

were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The laboratory reported a failed study set up on February 22, 2007. In that study, a recoverable virus titer of at least 10^4 was not achieved. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on April 12, 2007 and again on May 11, 2007. In these studies, recoverable virus titers of at least 10^4 were not achieved. The laboratory did not accept these assays. These data were also not used to evaluate efficacy of the product. Testing was repeated on July 25, 2007 using cells and media from an alternate source than used for the previous assays. See page 8 and Attachments I, II, and III of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

3. MRID 479124-03 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Adenovirus type 2" for Axen 30, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 6, 2008. Project Number A05943.

This study was conducted against Adenovirus type 2 (Strain Adenoid 6; ATCC VR-846), using A-549 cells (human lung carcinoma cells; ATCC CCL-185; propagated in-house) as the host system. Two lots (Lot Nos. P07271001 and P07302001) of the product, Axen 30, were tested according to ATS Labs Protocol No. IMS01121407.ADV (copy provided). The product was received ready-to-use, and transferred to spray bottles for testing. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the undersides of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.2°C at 52% relative humidity. For each lot of product, separate dried virus films were sprayed (3 sprays) with the product until thoroughly wet at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 3 or 5 minutes at 20.2°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. A-549 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

4. MRID 479124-04 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Murine Norovirus (MNV-1)" for Axen 30, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – August 25, 2008. Project Number A06613.

This study was conducted against Murine norovirus (Strain MNV-1.CW1; obtained from Washington University, St. Louis, MO), using RAW 264.7 cells (mouse macrophage cells; originally obtained from Washington University, St. Louis, MO; propagated in-house) as the host system. Two lots (Lot Nos. P07271001 and P07302001) of the product, Axen 30, were tested according to ATS Labs Protocol No. IMS01071108.MNV (copy provided). The product was received ready-to-use, and transferred to spray bottles for testing. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the undersides of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were sprayed (2 sprays) with the product until thoroughly wet at an unspecified distance from the carrier surface. The carriers were allowed to remain wet for 5 or 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Complete 2X Minimum Essential Medium. RAW 264.7 cells in multi-well culture dishes were inoculated in quadruplicate with 250 µL of the dilutions. The inoculum was allowed to adsorb for 60 minutes at room temperature. Following adsorption, the cultures were re-fed with MNV Overlay Agarose I and incubated for 2 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. Following incubation, the cultures were re-fed with MNV Overlay Agarose II containing neutral red stain and incubated for 4 hours at 36-38°C in a humidified atmosphere of 5-7% CO_2. Following incubation, the cultures were visually and microscopically observed for the presence or absence of viral specific plaques and cytotoxicity. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

5. MRID 479124-05 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Swine Influenza A (H1N1) virus" for Axen 30, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – October 26, 2009. Project Number A08284.

This study was conducted against Swine influenza A (H1N1) virus (Strain A/Swine/Iowa/15/30; ATCC VR-333), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. P09209001 and P09210001) of the product, Axen 30, were tested according to ATS Labs Protocol No. IMS01090109.SFLU (copy provided). The product was received ready-to-use, along with trigger spray nozzles. The stock virus culture contained 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the undersides of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 40% relative humidity. For each lot of product, separate dried virus films were sprayed (4 sprays) with the product until thoroughly wet at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 1 or 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and

2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

6. MRID 479124-06 "Germicidal and Detergent Sanitizing Action of Disinfectants," Test Organisms: *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538), for Axen 30, by Sally Nada. Study conducted at ATS Labs. Study completion date – October 4, 2005. Project Number A03193.

This study was conducted against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 2003.125.002, 2005.200.001, and 2005.210.001) of the product, Axen 30, were tested. The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method (modified) as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. [No product lot was specified as being at least 60 days old at the time of testing; however, the lot numbers appear to be date coded, which would make Lot No. 2003.125.002 at least 60 days old. The product was received ready-to-use. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC method, with the following exception: due to the unavailability of a 4.0 McFarland standard, visual turbidity was used as a measure. [The AOAC method states to standardize the culture to give an average of 10×10^9 organisms/mL.] The product was not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each product lot was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 25±1°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized product were plated in tryptone glucose extract agar. All plates were incubated for 48±4 hours at 35-37°C (which differs from the AOAC method specification of 48 hours at 35°C). The plates were stored for 1 day at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

Note: Testing deviated from AOAC method specifications with regard to culture preparation and subculture incubation. The deviations appear to be acceptable.

V RESULTS

MRID Number	Organism	Results			Dried Virus Count
			Lot No. P09209001	**Lot No. P09210001**	
479124-01	Influenza A (H1N1) virus 1 minute	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
	Influenza A (H1N1) virus 2 minutes	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.0}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
479124-05	Swine influenza A (H1N1) virus 1 minute	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
	Swine influenza A (H1N1) virus 2 minutes	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{6.0}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
			Lot No. 2006.003.001	**Lot No. 2007.008.002**	
479124-02	Respiratory syncytial virus 3 and 10 minutes	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
			Lot No. P07271001	**Lot No. P07302001**	
479124-03	Adenovirus type 2 3 minutes	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
	Adenovirus type 2 5 minutes	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
479124-04	Murine norovirus 5 minutes	10^{-1} dilution	Cytotoxicity	Complete inactivation	$10^{5.5}$ PFU_{50}/0.25 mL
		10^{-2} to 10^{-3} dilutions	Infectivity		
		10^{-4} to 10^{-8} dilutions	Complete inactivation		
		PFU_{50}/0.25 mL	$10^{2.75}$	$\leq 10^{0.5}$	
		Log reduction	≥ 2.75 $\log_{10}$	---	
	Murine Norovirus 10 minutes	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{6.2}$ PFU_{50}/0.25 mL
		10^{-2} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	
		PFU_{50}/0.25 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	≥ 4.75 $\log_{10}$	≥ 4.75 $\log_{10}$	

MRID Number	Organism	Lot No.	Total No. Surviving	Microbes Initially Present	Percent Reduction
			(CFU/mL)		
479124-06	*Escherichia coli*	2003.125.002	<10	9.4×10^7	>99.999
		2005.200.001	<10	9.4×10^7	>99.999
		2005.210.001	<10	9.4×10^7	>99.999
	Staphylococcus aureus	2003.125.002	<10	8×10^7	>99.999
		2005.200.001	<10	8×10^7	>99.999
		2005.210.001	<10	8×10^7	>99.999

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Axen 30, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 1% organic soil load for the following contact times:

Influenza A (H1N1) virus	1 (and 2) minute(s)	MRID 479124-01
Respiratory syncytial virus	3 (and 10) minutes	MRID 479124-02
Adenovirus type 2	3 (and 5) minutes	MRID 479124-03
Swine influenza A (H1N1) virus	1 (and 2) minute(s)	MRID 479124-05

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

2. The submitted efficacy data (MRID 479124-04) support the use of the product, Axen 30, as a disinfectant with virucidal activity against Murine norovirus on hard, non-porous surfaces in the presence of a 5% organic soil load for a 10-minute contact time. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was observed in the 10^{-1} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

Note: Efficacy of the product was not demonstrated against Murine Norovirus for a 5-minute contact time.

3. The submitted efficacy data support the use of the product, Axen 30, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces for a 30-second contact time:

Escherichia coli	MRID 479124-06
Staphylococcus aureus	MRID 479124-06

Bacterial reductions of at least 99.999 percent over the parallel control were observed within 30 seconds. One of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

Note: The "Comments on the Submitted Efficacy Studies" section of this report identifies AOAC method deviations with regard to culture preparation and subculture incubation. The deviations appear to be acceptable.

VII RECOMMENDATIONS

1. The proposed label claims that the product, SDC3A, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for the contact time listed:

Influenza A (H1N1) virus	1 minute
Swine influenza A (H1N1) virus	1 minute
Respiratory syncytial virus	3 minutes
Adenovirus type 2	3 minutes
Murine norovirus	10 minutes

These claims are acceptable as they are supported by the submitted data. Note that the reference to Influenza A virus (H3N2) on page 4 of the proposed label must be deleted.

2. The proposed label claims that the product, SDC3A, is an effective sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces for a 60-second contact time:

Escherichia coli
Staphylococcus aureus

These claims are acceptable as they are supported by the submitted data. Note that the reference to *Escherichia coli* O157:H7 on page 4 of the proposed label must be revised to read "*Escherichia coli.*"

3. The proposed label states that the product can be used as a deodorizer. The label must be revised to provide adequate dosage recommendations and complete directions for use of the product as a deodorizer.

4. The following revisions to the proposed label must be made:

- On page 1 of the proposed label, identify the EPA registration number as "72977-5."
- On page 8 of the proposed label, delete the reference to "Equine herpes virus type 1."

5. The following revisions to the proposed label are required:

- On page 2 of the proposed label, delete the following surfaces as the product is not for use on utensils, dishes, or glassware: animal feeding dishes, baby bottles, pacifiers, and pet bowls.
- On page 6 of the proposed label, change "either into or in contact with the human body, either into or in contact with the bloodstream" to read "either into or in contact with the bloodstream."